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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/819,371	03/28/2001	Kohji Egawa	31508	4334

7590 04/21/2006
John M. Collins
HOVEY, WILLIAMS, TIMMONS & COLLINS
Suite 400
2405 Grand Blvd.
Kansas City, MO 64108

EXAMINER

CANELLA, KAREN A

ART UNIT PAPER NUMBER

1643

DATE MAILED: 04/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/819,371

Applicant(s)

EGAWA, KOHJI

Examiner

Karen A. Canella

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 60-72 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 60,62-68 and 71 is/are allowed.
- 6) ☐ Claim(s) 69 and 70 is/are rejected.
- 7) ☐ Claim(s) 61 and 72 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: attachment.

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DETAILED ACTION

Claims 60, 61, 64-72 have been amended. Claims 60-72 are pending and under consideration.

Text of title 35, U.S. code not found in this action, can be found in a prior action.

Claims 61, 70 and 72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 61 recites "cancer cell specific HLA-F antigen is obtained by expressing DNA comprising SEQ ID NO:3". Claim 70 recites "cancer cell specific HLA-F antigen is obtained by expressing DNA comprising SEQ ID NO:2". Claim 72 recites "cancer cell specific HLA-F antigen is obtained by expressing DNA comprising SEQ ID NO:1". Independent claims 60, 69 and 71 require the HLA-F antigen of SEQ ID NO:6, SEQ ID NO:3 and SEQ ID NO:4. It is unclear how claims 61, 70 and 72 further limit claims 60, 69 and 71. The scope of claims 62, 70 and 72 appears to be the same as the scope of claims 60, 69 and 71, respectively.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent,; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 69 and 70 are rejected under 35 U.S.C. 102(e) as being anticipated by Morin et al (WO 01/75177, priority to April 3, 2000).

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Claim 69 is drawn to a method of diagnosing a cancer that is non-specific to various organs comprising the steps of contacting a cancer cell specific HLA-F antigen comprising SEQ ID NO:5 with the body fluid of a subject and detecting the formation of an immune complex with antibodies in said body fluid.

Morin et al disclose the ovarian cancer antigen of SEQ ID NO:82 (page 13, line 19) which is identical to the instant SEQ ID NO:5. Morin et al teach (page 16, lines 1-7)

In addition, since rapid tumor cell destruction often results in autoantibody generation, the ovarian tumor markers of the invention may be used in serological assays (e. g., an ELISA test of a subject's serum) to detect autoantibodies against ovarian tumor markers in a subject. Ovarian tumor marker polypeptide-specific autoantibody levels that are at least about 3-fold higher (and preferably at least 5-fold or 7-fold higher, most preferably at least 10-fold or 20-fold higher) than in a control sample are indicative of ovarian cancer.

The disclosure of an ELISA test fulfills the specific embodiment requiring the application of a secondary antibody. The claim objective of diagnosing cancer that is non-specific to various organs fails to exclude the detection of ovarian cancer because the active method disclosed by Morin et al comprises the same steps as the instant method, the only difference being Morin et al did not disclose SEQ ID NO:82 as a "universal" cancer antigen. Further, Morin et al fulfills the specific limitation of claim 70 because the HLA-F antigen of claim 70 is obtained by the process of expressing the DNA of SEQ ID NO:2 and the M.P.E.P. (2113) states

*PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE
MANIPULATIONS OF THE RECITED STEPS, ONLY THE STRUCTURE
IMPLIED BY THE STEPS*

Thus the cancer cell specific antigen obtained by expressing the DNA sequence of SEQ ID NO:2 is the same as the cancer cell antigen of SEQ ID NO:82 as disclosed by Morin et al.

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All other rejections and objections as set forth in the previous Office action are withdrawn in light of applicants amendments.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 11 am to 10 pm, except Wed, Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.

4/14/2006


KARENA CANELLA PH.D
PRIMARY EXAMINER

GenCore version 5.1.7
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OM protein - protein search, using sw model

Run on: April 7, 2006, 12:59:38 ; Search time 91.7626 Seconds
(without alignments)
1247.624 Million cell updates/sec

Title: US-09-819-371-5
Perfect score: 1496
Sequence: 1 GSHSLRYFSTAVSRPGRGEP.....QRYTCHVQHEGLPQPLILRW 274

Scoring table: BLOSUM62

Gapop 10.0 , Gapext 0.5

Searched: 1867569 seqs, 417829326 residues

Total number of hits satisfying chosen parameters: 1867569

Minimum DB seq length: 0
Maximum DB seq length: 2000000000

Post-processing: Minimum Match 0%
Maximum Match 100%
Listing first 45 summaries

Database : Published Applications AA Main:
1: /cgn2_6/ptodata/1/pubpaa/US07_PUBCOMB.pep.*
2: /cgn2_6/ptodata/1/pubpaa/US08_PUBCOMB.pep.*
3: /cgn2_6/ptodata/1/pubpaa/US09_PUBCOMB.pep.*
4: /cgn2_6/ptodata/1/pubpaa/US10A_PUBCOMB.pep.*
5: /cgn2_6/ptodata/1/pubpaa/US10B_PUBCOMB.pep.*
6: /cgn2_6/ptodata/1/pubpaa/US11_PUBCOMB.pep.*

Pred. No. is the number of results predicted by chance to have a score greater than or equal to the score of the result being printed, and is derived by analysis of the total score distribution.

SUMMARIES

Result No.	Score	Query Match	Length	DB ID	Description
1	1496	100.0	274	3	US-09-819-371-5
2	1496	100.0	362	4	US-10-257-021-82
3	1496	100.0	362	5	US-10-631-467-624
4	1496	100.0	442	4	US-10-408-765A-1887
5	1491	99.7	677	5	US-10-450-763-57085
6	1489	99.5	362	3	US-09-819-371-4
7	1311	87.6	271	3	US-09-925-301-1431
8	1221	81.6	362	5	US-10-631-467-728
9	1205	80.5	366	5	US-10-287-436A-101
10	1205	80.5	366	5	US-10-287-436A-162
11	1205	80.5	366	5	US-10-287-436A-1257
12	1205	80.5	366	5	US-10-287-436A-1267
13	1196	79.9	362	5	US-10-287-436A-120
14	1196	79.9	362	5	US-10-287-436A-1260
15	1193	79.7	365	5	US-10-741-600-941
16	1184	79.1	326	4	US-10-380-980-7
17	1184	79.1	338	4	US-10-741-601-380
18	1184	79.1	338	4	US-10-741-601-388
19	1184	79.1	338	5	US-10-741-600-1134
20	1184	79.1	338	5	US-10-741-600-1138
21	1184	79.1	338	5	US-10-482-029-110
22	1184	79.1	343	4	US-10-741-601-379
23	1184	79.1	343	5	US-10-741-600-1139
24	1183	79.1	365	5	US-10-287-436A-179
25	1183	79.1	365	5	US-10-287-436A-1268
26	1175	78.5	365	4	US-10-741-601-325
27	1175	78.5	365	4	US-10-741-601-326

28	1175	78.5	365	5	US-10-741-600-939	Sequence 939, App
29	1175	78.5	365	5	US-10-741-600-940	Sequence 940, App
30	1174.5	78.5	373	4	US-10-093-463-78	Sequence 78, Appl
31	1174.5	78.5	379	4	US-10-210-172-160	Sequence 160, App
32	1164	77.8	215	3	US-09-819-371-6	Sequence 6, Appl
33	1158	77.4	364	4	US-10-093-463-80	Sequence 80, Appl
34	1154	77.1	34	3	US-10-138-888-23	Sequence 23, Appl
35	1153	77.1	280	4	US-10-073-300-6	Sequence 6, Appl
36	1153	77.1	280	4	US-10-075-257-6	Sequence 6, Appl
37	1153	77.1	415	4	US-10-073-300-5	Sequence 5, Appl
38	1153	77.1	415	4	US-10-075-257-5	Sequence 5, Appl
39	1153	77.1	421	6	US-11-040-686-42	Sequence 42, Appl
40	1153	77.1	510	4	US-10-108-511-5	Sequence 5, Appl
41	1153	77.1	510	5	US-10-482-532-5	Sequence 5, Appl
42	1133.5	75.8	389	4	US-10-108-511-2	Sequence 2, Appl
43	1133.5	75.8	389	5	US-10-482-532-2	Sequence 2, Appl
44	1131	75.6	371	4	US-10-085-198-72	Sequence 72, Appl
45	1131	75.6	371	4	US-10-210-172-156	Sequence 156, App

ALIGNMENTS

RESULT 1
US-09-819-371-5
; Sequence 5, Application US/09819371
; Publication No. US20040053344A1
; GENERAL INFORMATION:
; APPLICANT: Egawa, Kohji
; TITLE OF INVENTION: Cancer Cell-Specific HLA-F Antigen and a Diagnostic Method of C
; FILE REFERENCE: 30815
; CURRENT APPLICATION NUMBER: US/09/819,371
; CURRENT FILING DATE: 2002-03-15
; NUMBER OF SEQ ID NOS: 6
; SOFTWARE: Patentin version 3.0
; SEQ ID NO 5
; LENGTH: 274
; TYPE: PRT
; ORGANISM: Homo sapiens
US-09-819-371-5

Query Match	100.0%;	Score 1496;	DB 3;	Length 274;
Best Local Similarity	100.0%;	Pred. No. 1e-135;		
Matches 274;	Conservative 0;	Mismatches 0;	Indels 0;	Gaps 0;
Qy	1	GSHSLRYFSTAVSRPGRGEP	RYIAVEYVDDTQFLRPSDAAIPRMEPRPWPVEQGPQYW	60
Db	1	GSHSLRYFSTAVSRPGRGEP	RYIAVEYVDDTQFLRPSDAAIPRMEPRPWPVEQGPQYW	60
Qy	61	EWTTGYAKANAQTRVALRNLRLRYN	QSEAGSHLTQGMGCDMGPDGRLLRGYHAYDG	120
Db	61	EWTTGYAKANAQTRVALRNLRLRYN	QSEAGSHLTQGMGCDMGPDGRLLRGYHAYDG	120
Qy	121	KOYISLNEDLSRWTAADTVAQITQRF	YEAEEYAEPRTYLGECELELLRYLNGKETLQ	180
Db	121	KOYISLNEDLSRWTAADTVAQITQRF	YEAEEYAEPRTYLGECELELLRYLNGKETLQ	180
Qy	181	RADPPKAHVAHPISDHEATLRCWALG	FTPAETLTWQRDGEQTQTELVTETPAGDGT	240
Db	181	RADPPKAHVAHPISDHEATLRCWALG	FTPAETLTWQRDGEQTQTELVTETPAGDGT	240
Qy	241	FKQWAAVVPSPGEQRYTCHVQHEGLP	QPLILRW	274
Db	241	FKQWAAVVPSPGEQRYTCHVQHEGLP	QPLILRW	274

RESULT 2
US-10-257-021-82
; Sequence-82, Application US/10257021
; Publication No. US20030211498A1
; GENERAL INFORMATION:
; APPLICANT: Morin, Patrice J.

Attachment to 20060414

```

; APPLICANT: Sherman-Baust, Cheryl A.
; APPLICANT: Pizer, Ellen S.
; APPLICANT: Hough, Colleen D.
; TITLE OF INVENTION: TUMOR MARKERS IN OVARIAN CANCER
; FILE REFERENCE: 14014.036902
; CURRENT APPLICATION NUMBER: US/10/257,021
; PRIOR FILING DATE: 2002-10-03
; PRIOR APPLICATION NUMBER: PCT/US01/10947
; PRIOR FILING DATE: 2001-04-03
; PRIOR APPLICATION NUMBER: 60/194,336
; PRIOR FILING DATE: 2000-04-03
; NUMBER OF SEQ ID NOS: 147
; SOFTWARE: FastSeq for Windows Version 4.0
; SEQ ID NO 82
; LENGTH: 362
; TYPE: PRT
; ORGANISM: Homo sapiens
US-10-257-021-82

Query Match      100.0%; Score 1496; DB 4; Length 362;
Best Local Similarity 100.0%; Pred. No. 1.5e-135;
Matches 274; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

QY 1 GSHSLRYFSTAVSRPGRGEPRIAYEYVDDTQFLRFDSDAAIPRMEPREPWVEQSGPQYW 60
DB 22 GSHSLRYFSTAVSRPGRGEPRIAYEYVDDTQFLRFDSDAAIPRMEPREPWVEQSGPQYW 81
QY 61 EWTGTAKANAQTDRLVALNRLRRYNQSEAGSHTLQGMGCDMGDPGRLLRGYHQHAYDG 120
DB 82 EWTGTAKANAQTDRLVALNRLRRYNQSEAGSHTLQGMGCDMGDPGRLLRGYHQHAYDG 141
QY 121 KYIISLNEDLSWTAADTVAQITQRFYEABEYAEFRYTLGEGCELELLRRLYENGKETLQ 180
DB 142 KYIISLNEDLSWTAADTVAQITQRFYEABEYAEFRYTLGEGCELELLRRLYENGKETLQ 201
QY 181 RADPPKAHVAHPISDHEATLRCWALGFYPABITLTTWQDGEEOQDTDELVETRPAGDGT 240
DB 202 RADPPKAHVAHPISDHEATLRCWALGFYPABITLTTWQDGEEOQDTDELVETRPAGDGT 261
QY 241 FQKWAADVVPSEGEORYTCHVQHEGLPQPLILRW 274
DB 262 FQKWAADVVPSEGEORYTCHVQHEGLPQPLILRW 295

RESULT 4
US-10-408-765A-1887
; Sequence 1887, Application US/10408765A
; Publication No. US20040101874A1
; GENERAL INFORMATION:
; APPLICANT: Ghosh, Soumitra S.
; APPLICANT: Pabry, Eoin D.
; APPLICANT: Zhang, Bing
; APPLICANT: Gibson, Bradford W.
; APPLICANT: Taylor, Steven W.
; APPLICANT: Glenn, Gary M.
; APPLICANT: Warnock, Dale E.
; TITLE OF INVENTION: TARGETS FOR THERAPEUTIC INTERVENTION
; FILE REFERENCE: IDENTIFIED IN THE MITOCHONDRIAL PROTEOME
; CURRENT APPLICATION NUMBER: US/10/408,765A
; CURRENT FILING DATE: 2003-04-04
; NUMBER OF SEQ ID NOS: 3077
; SOFTWARE: FastSeq for Windows Version 4.0
; SEQ ID NO 1887
; LENGTH: 442
; TYPE: PRT
; ORGANISM: Homo sapiens
US-10-408-765A-1887

Query Match      100.0%; Score 1496; DB 4; Length 442;
Best Local Similarity 100.0%; Pred. No. 2e-135;
Matches 274; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

QY 1 GSHSLRYFSTAVSRPGRGEPRIAYEYVDDTQFLRFDSDAAIPRMEPREPWVEQSGPQYW 60
DB 22 GSHSLRYFSTAVSRPGRGEPRIAYEYVDDTQFLRFDSDAAIPRMEPREPWVEQSGPQYW 81
QY 61 EWTGTAKANAQTDRLVALNRLRRYNQSEAGSHTLQGMGCDMGDPGRLLRGYHQHAYDG 120
DB 82 EWTGTAKANAQTDRLVALNRLRRYNQSEAGSHTLQGMGCDMGDPGRLLRGYHQHAYDG 141
QY 121 KYIISLNEDLSWTAADTVAQITQRFYEABEYAEFRYTLGEGCELELLRRLYENGKETLQ 180
DB 142 KYIISLNEDLSWTAADTVAQITQRFYEABEYAEFRYTLGEGCELELLRRLYENGKETLQ 201
QY 181 RADPPKAHVAHPISDHEATLRCWALGFYPABITLTTWQDGEEOQDTDELVETRPAGDGT 240
DB 202 RADPPKAHVAHPISDHEATLRCWALGFYPABITLTTWQDGEEOQDTDELVETRPAGDGT 261
QY 241 FQKWAADVVPSEGEORYTCHVQHEGLPQPLILRW 274
DB 262 FQKWAADVVPSEGEORYTCHVQHEGLPQPLILRW 295

RESULT 5
US-10-450-763-57085
; Sequence 57085, Application US/10450763
; Publication No. US20050196754A1
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